The NICE guideline

What's the problem?

A landmark event of 2007 was the publication of the National Institute for Clinical Excellence (NICE) Clinical Guideline 53: the final word on the diagnosis and management of "CFS/ME". However, the storm of protest from Registered Stakeholders, including ME Research UK, over the initial draft guideline — more than double the usual volume of replies, with a higher than usual proportion coming from patients, according to Dr Fred Nye in a subsequent letter in the Journal of Infection — has not abated with publication of the final document, and it is important to ask why. Is Guideline 53 really so bad?

Like the curate's egg, some parts are palatable. The NICE clinical diagnosis now requires "*post-exertional malaise and/or fatigue… with slow recovery over several days*" to be present. Also, doctors "*should acknowledge the reality and impact of the condition and symptoms*", and should look out for "red flag" signs and symptoms that might be caused by other conditions in both existing and newly diagnosed patients.

But because — to quote the Guideline — "*there is no known pharmacological treatment or cure… symptoms… should be managed as in usual clinical practice*", NICE has been forced to flag up cognitive-behavioural approaches for the specialist management of the illness, approaches generally considered to be non-specific in their effect, and to be non-curative including by Guideline 53 itself (section 6.3.8, p. 252). Moreover, the Guideline has based this decision on randomised controlled trial evidence which is skewed towards a small group of mildly positive cognitive-behavioural clinical trials (see page 9 sidebar of this issue), while devaluing other evidence from basic scientific studies and surveys of patients' experiences.

In most illnesses, cognitive-behavioural approaches are adjuncts to the contemporaneous biomedical research that spearheads the drive towards a cure. Yet, in ME/CFS, they stand centre-stage, with the result that it is the only physical condition for which cognitive behavioural therapy is flagged up as a primary specialist management approach in a NICE guideline (see the sidebar on the left). The table below — from Guideline 53's companion National Costing Report — shows the cost to the country of implementing the guidance in full: £45.2 million over 5 years.

Like almost all patient-based charities and ME support groups in the UK, we think that NICE Guideline 53 is "unfit for purpose" in its final form. So the battle goes on to move basic scientific and clinical research centre-stage, into the spotlight presently occupied by psychosocial models in the minds of opinion formers and healthcare professionals. ●

Cost increase of implementing Guideline 53

Recommendations	*Recurrent annual costs (£m)*	*Non-recurrent costs (£m)*
Cognitive behavioural therapy	*1.03*	*7.30*
Graded exercise therapy	*0.58*	*4.10*
Activity management strategies	*0.92*	*6.46*
Activity management programmes	*1.22*	*8.59*
Total	***3.75***	***26.45***

TABLE

NICE Clinical Guidance recommendations on the use of CBT for 19 different clinical conditions

Is CBT postulated to be a main intervention for the condition (Clinical Guideline number)?	
Anxiety (22)	YES
Bipolar disorder (38)	YES
Depression (23)	YES
Eating disorders (9)	YES
Obsessive-compulsive disorder (31)	YES
Schizophrenia (1)	YES
Chronic pulmonary disease (12)	NO
Dementia (42)	NO
Dyspepsia (17)	NO
Type 1 diabetes (15)	NO
Hypertension (34)	NO
Lung cancer (24)	NO
Multiple sclerosis (8)	NO
The epilepsies (20)	NO
Parkinson's disease (35)	NO
Familial breast cancer (41)	NO
Tuberculosis (33)	NO
Chronic heart failure (5)	NO
CFS/ME (53)	**YES**